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| APPLICATION NO.                  | ON NO. FILING DATE FIRST NAMED INV |                  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|----------------------------------|------------------------------------|------------------|-------------------------|------------------|
| 09/913,521 08/13/2001            |                                    | Shinji Matsuyama | 44324.013100            | 9592             |
| 75                               | 90 01/07/2003                      |                  |                         |                  |
| Eugene C Rzu                     |                                    | EXAMINER         |                         |                  |
| Greenberg Trau<br>885 Third Aven | ue 21st Floor                      | ANGELL, JON E    |                         |                  |
| New York, NY 10022               |                                    | ART UNIT         | PAPER NUMBER            |                  |
|                                  |                                    |                  | 1635                    |                  |
|                                  |                                    |                  | DATE MAILED: 01/07/2003 | 15               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| · ·   |  | Арр                 | lication No.                        | Applicant(s)  |  |  |  |
|---|--|---------------------|-------------------------------------|---|--|--|--|
|   |  | 09/9                | 913,521                             | MATSUYAMA ET AL.  |  |  |  |
| Office Action Summary   |  |                     | miner                               | Art Unit  |  |  |  |
| _   |  |                     |                                     | •   |  |  |  |
|   | J. Eric Angell 1635  The MAILING DATE of this communication appears on the cover sheet with the correspondence address |                     |                                     |   |  |  |  |
| Period for Reply  |  |                     |                                     |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |  |                     |                                     |   |  |  |  |
| 1)🖂   | Responsive to communication(s) file  | ed on 18 Octobe     | er 2002 .                           |   |  |  |  |
| 2a) <u></u>   |  | 2b)⊠ This action    |                                     |   |  |  |  |
| 3)  |  |                     |                                     | rs prosecution as to the merits is                            |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |  |                     |                                     |   |  |  |  |
| 4)⊠   | 4)⊠ Claim(s) <u>1-29</u> is/are pending in the application.  |                     |                                     |   |  |  |  |
| 4a) Of the above claim(s) 4.5,21,22 and 27-29 is/are withdrawn from consideration.  |  |                     |                                     |   |  |  |  |
| 5)⊠ Claim(s) <u>1,2,16-20,23 and 24</u> is/are allowed.   |  |                     |                                     |   |  |  |  |
| 6)⊠ Claim(s) <u>25 and 26</u> is/are rejected.  |  |                     |                                     |   |  |  |  |
| 7)⊠   | 7)⊠ Claim(s) <u>3 and 6-15</u> is/are objected to.   |                     |                                     |   |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  Application Papers   |  |                     |                                     |   |  |  |  |
| 9)[] 7  | 9)☐ The specification is objected to by the Examiner.  |                     |                                     |   |  |  |  |
| 10)∐ T  | he drawing(s) filed on is/are:   | a) accepted or l    | b) objected to by the               | Examiner.   |  |  |  |
|   | Applicant may not request that any object  |                     |                                     |   |  |  |  |
| 11) 🗌 T   | he proposed drawing correction filed   |                     |                                     | pproved by the Examiner.                                      |  |  |  |
|   | If approved, corrected drawings are required in reply to this Office action.   |                     |                                     |   |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |  |                     |                                     |   |  |  |  |
| Priority u  | nder 35 U.S.C. §§ 119 and 120  |                     |                                     |   |  |  |  |
| 13) 🗌 🛚   | Acknowledgment is made of a claim  | for foreign priorit | y under 35 U.S.C. § 1               | 19(a)-(d) or (f).   |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |                     |                                     |   |  |  |  |
|   | 1. Certified copies of the priority documents have been received.  |                     |                                     |   |  |  |  |
| :   | 2. Certified copies of the priority documents have been received in Application No                                     |                     |                                     |   |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                     |                                     |   |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |  |                     |                                     |   |  |  |  |
| <ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>  |  |                     |                                     |   |  |  |  |
| Attachment(s)   |  |                     |                                     |   |  |  |  |
| 2) Notice   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PT ation Disclosure Statement(s) (PTO-1449) Pa  | O-948)<br>per No(s) | 4) Interview Sum 5) Notice of Infor | mary (PTO-413) Paper No(s) mal Patent Application (PTO-152) . |  |  |  |

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#### **DETAILED ACTION**

1. This Action is in response to the communication filed on 10/18/02, as Paper No. 14. Claims 1, 18 and 27 have been amended. Claims 1-29 are pending in the application. Claims 4, 5, 21, 22 and 27-29 are withdrawn from consideration as set forth in the previous office action. Claims 1-3, 6-20, and 23-26 are addressed herein.

2. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

### Claim Objections

- 3. Claim 3 is objected to because of the following informalities: claim 3 depends on claim 17. A claim cannot depend on a later numbered claim. Canceling claim 3 and adding a new claim comprising language similar to claim 3 wherein the new claim depends on claim 17 would obviate this rejection. It is respectfully pointed out that claims 1-29 are pending in the application; therefore, any new claims must start with claim 30.
- 4. Claim 6 is objected to because of the following informalities: claim 6 appears to contain a grammatical error. Specifically, claim 6 recites, "based on the whole phosphodiester bonds". Amending the claim to recite, "based on the total number of phosphodiester bonds" would obviate this objection. Appropriate correction is required.
- 5. Claim 7 is objected to because of the following informalities: claim 7 appears to contain a grammatical error. Specifically, claim 7 recites, "or analogue thereof" several times.

  Amending the claim to recite, " or an analogue thereof" would obviate this objection.

  Appropriate correction is required.

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- 6. Applicant is advised that should claim 3 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 7. Applicant is advised that should claim 7 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 8. Applicant is advised that should claim 8 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 9. Applicant is advised that should claim 10 be found allowable, claims 18, 19 and 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 10. Applicant is advised that should claim 15 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

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application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Claims 8-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim, here the instant claims depends on the multiple dependent claim 7. See MPEP § 608.01(n).

Accordingly, the claims 8-15 have not been further treated on the merits. Appropriate correction is required.

# Claim Rejections - 35 USC § 112

- 12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 13. Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 14. Claim 25 recites the limitation "the chain-shortened polynucleotide or salt thereof according to claim 18". There is insufficient antecedent basis for this limitation in the claim.
- 15. Claim 26 recites the limitation "the double-stranded chain-shortened polynucleotide or salt thereof according to claim 18". There is insufficient antecedent basis for this limitation in the claim.

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### Response to Arguments

The rejection of claims under 35 USC 102 and 103 are withdrawn. Applicants have amended the claims such that the percent of 2'-5' phosphodiester bonds present in the polynucleotides does not exceed 3 percent. The references do not teach that the percentage of 2'-5' phosphodiester bonds does not exceed 3 percent. Additionally, there is no disclosure indicating any motivation to make a polynucleotide comprising about 0.1 percent to 3 percent 2'-5' phosphodiester bonds.

The rejection of claims under 35 USC 112, second paragraph have been withdrawn in view of applicants arguments. However, claims 25 and 36 have been rejected under 35 USC 112, second paragraph for the reasons set forth above.

### Allowable Subject Matter

16. Claims 1, 2, 16-20, 23 and 24 appear to be allowable as the prior art does not teach a polynucleotide comprising about 0.1 percent to 3 percent 2'-5' phosphodiester bonds, nor does the prior art indicate any motivation to make such a polynucleotide. The prior art (as evidenced by Kandimalla) indicates that increasing the number of 2'-5' phosphodiester linkages increases the stability of the polynucleotide in the presence of nucleases, and decreases the immune stimulation but also have a lower affinity for a target site (see Kandimalla, column 5), but does not indicate any particular advantage to making a polynucleotide having about 0.1% to 3% 2'-5' phosphodiester bonds. It is pointed out that many of the claims (such as those mentioned in the claim objections above) appear to be substantial duplicates of other claims. Any claim which is

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a substantial duplicate of an allowable claim will be objected to; therefore, it is recommended that all pending claims be reviewed with respect to possible duplicate claims.

17. It is also pointed out that claims 1-29 are pending in the application. Claims 4, 5, 21, 22 and 27-29 have been withdrawn from consideration as being drawn to non-elected invention(s), but are still pending and must be cancelled before an notice of allowability can be issued.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell December 26, 2002

DAVE T. NGUYEN PRIMARY EXAMINER